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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,625

04/04/2006

Tine Hoff

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9296

25908 7590 12/10/2009  
NOVOZYMES NORTH AMERICA, INC.  
500 FIFTH AVENUE  
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NEW YORK, NY 10110

EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT

PAPER NUMBER

1636

NOTIFICATION DATE

DELIVERY MODE

12/10/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patents-US-NY@novozymes.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/574,625	<b>Applicant(s)</b> HOFF, TINE	
	<b>Examiner</b> NANCY VOGEL	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 23,25,26,28,30,31,33,34,36,38,39 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23, 25,26,28,30,31,33,34,36,38,39 and 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 23, 25, 26, 28, 30, 31, 33, 34, 36, 38, 39, 41-44 are pending in the case.

### ***Response to Amendment***

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are no new grounds of rejection that were not necessitated by applicants' amendment and therefore, this action is final.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23, 25, 26, 28, 33, 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action mailed 3/3/09. Applicants have argued that the Example 16 discloses reduction to practice of a single nucleic acid used to transform mitochondria,,

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but that the level of skill and knowledge in the art is such that those skilled in the art know of numerous nucleic acids that could be complexed with compound X to be used in the claimed method of to transform the mitochondria. This argument is not considered to be relevant to the instant rejection, since the rejection was based on lack of written description for the genus of secretion stress inducible promoters, and secretion stress inducible promoters which in its normal position is linked to a gene encoding a polypeptide which has at least 70% or 80% homology to the amino acid sequence of SEQ ID NO:2 (page 4 of the Office action). Applicants have not addressed this point of the rejection in their arguments. Therefore, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 39, 43, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38, 39, 43, 44 are dependent on cancelled claim 24, and therefore the intended subject matter cannot be determined.. This rejection was necessitated by applicant's amendment.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23, 25, 26, 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (Embo J. 16, 6394-6406, 1997).

This rejection is maintained essentially for the reasons set forth previously in the Office action of 3/3/09.

Applicants have argued that Jones et al. discloses a bacterial host cell comprising one or two known genes where none encode secreted proteins, while monitoring a secretion stress inducible protein operatively linked to a reporter (degP-lacZ). However, as was previously stated, a "library" may be considered to be more than one genes. Furthermore, there is no limitation in the claims stating that known genes may not be screened. Furthermore, whether the genes actually encode a secreted protein or not is not relevant, since the claim is directed to a method of screening only. Therefore, the rejection is maintained.

***Claim Rejections - 35 USC § 103***

Claims 30, 31, 33, 34, 36, 41, 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesley et al. (Protein Eng. 2002, 15:153-160) or Waldo (Curr. Opin. Chem. Biol. 2003, 7:33-38) in view of Noone et al. (J. Bacteriol. 183, b2, 2001, 654-663).

. This rejection is maintained essentially for the reasons set forth previously in the Office action of 3/3/09.

Applicants argue that Lesley and Waldo relate to the expression of a few well-known non-secreted (membrane) proteins, and that Noone "merely discloses the secretion-stress promoters employed in the instant invention". However, it is maintained that a library may be comprised of a few members, and furthermore, the fact that genes which are known are screened is not relevant, since there is no limitation in the claims reciting that the genes that are screened must be "unknown". Furthermore, the fact that none of the references teaches the entire claimed method does not obviate the obviousness rejection, which is based on consideration of the references taken together.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

NV  
12/5/09

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